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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,557	05/24/2001	David Beach	GNCA-P02-007	4804

28120 7590 03/28/2003

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EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/28/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,557

Applicant(s)

BEACH ET AL.

Examiner

Shar Hashemi

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,9,10 and 12-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 3, 4, 9, 10, 12-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims Status

1. Claims 2, 5-8 and 11 have been canceled.

Claims 1, 3, 4, 9, 10, 12-42 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I in Paper No. 13 is acknowledged. The traversal is on the ground(s) that (1) claims of Groups I-IV as well as the ungrouped new claims 26-40 are all directed to the mechanism of inactivating a target gene by double stranded RNA, (2) Groups I and II both belong to class 435, subclass 6, and (3) some claims in one group depend on claim a claim in a different group. This is not found persuasive because all of the Inventions are not drawn to a method for attenuating expression of a target gene utilizing dsRNA. For example, Invention IV is drawn to a method of conducting a drug discovery business comprising a step of formulating a pharmaceutical preparation. In addition, the ungrouped new claims 26-42 are directed to several Inventions. Therefore, the examination of multiple inventions imposes a substantial burden.

The following requirement is still deemed proper and is therefore made FINAL.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 3, 4, 9, 10, 12-15, and 26-29, drawn to a method for attenuating expression of a target gene classified in class 424, subclass 93.2.

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- II. Claim 16, drawn to an assay for identifying nucleic acid sequences, classified in class 435, subclass 7.1.
- III. Claims 17-19, drawn to a method of conducting a drug discovery business, classified in class 514, subclass 1.
- IV. Claims 20-22, drawn to a method for attenuating expression of a target gene utilizing a hairpin nucleic acid, classified in class 424, subclass 93.2.
- V. Claims 23-25, drawn to a transgenic animal, classified in class 800, subclass 3.
- VI. Claims 30-40, drawn to an isolated guide RNA, classified in class 435, subclass 194.
- VII. Claims 41 and 42, drawn to a method of generating knockout cells, classified in class 435, subclass 320.1.

4. The inventions are distinct, each from the other because of the following reasons:

Restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I, II, III, IV and VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires the search of methods for attenuating expression utilizing double stranded RNA whereby a complementary guide nucleotide sequence hybridizes to a portion of a target gene, which is not required by groups II, III, IV and VII. Invention II requires the search of assays for identifying nucleic acid sequences utilizing a library, which is not required by groups I, III, IV and VII. Invention III requires the search of methods for conducting a drug discovery whereby a pharmaceutical composition is formulated, which is not required by groups I, II, IV

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and VII. Invention IV requires the search of methods for attenuating expression utilizing a hairpin nucleic acid comprising an inverted repeat, which is not required by groups I, II, III and VII. Invention VII requires the search of methods for generating knockout cells, which is not required by groups I, II, III, and IV. Therefore, a search and examination of all five methods in one patent application would result in an undue burden, since the searches for the five methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions VI and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated guide RNA of Group VI can be used in materially different methods, such as RT-PCR and Northern Blot analysis.

Invention V is unrelated to Inventions I-IV and VI-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention V has different function such as the use of transgenic animal models to study growth and development or to study pathophysiology.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other groups, restriction for examination purposes as indicated is proper.

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CONCLUSION

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703) 305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.



Ethan Whisenant, Ph.D.
Primary Examiner

March 25, 2003

